

Brofemin

Oral suspension

COMPOSITION AND EXCIPENT: Each 5ml of oral Suspension Contains: Ibuprofen 100mg
PHARMACOLOGY: Ibuprofen is a non-steroidal anti-inflammatory agent that possesses analgesic and antipyretic activities. Its mode of action, like that of other non-steroidal anti-inflammatory agents, is not completely understood, but may be related to prostaglandin synthetase inhibition.

Ibuprofen has shown anti-inflammatory, analgesic and antipyretic activity in both animal and human studies. These properties provide symptomatic relief of inflammation and pain in rheumatoid arthritis, osteoarthritis and allied conditions.

PHARMACOKINETICS:

Absorption: Ibuprofen is well absorbed after oral administration. Single doses of 200 mg taken on an empty stomach by volunteers produced peak serum levels after approximately 45 minutes. When taken after food, absorption was slower, peak levels appearing at 1.5 to 3 hours.
Distribution: Apparent volume of distribution is 0.14 L/kg. Ibuprofen and its metabolites readily cross the placental barrier in pregnant rabbits and rats. It is not known if ibuprofen enters the CSF or is excreted in milk.

Protein binding: 99% of ibuprofen is protein bound. The high protein binding of ibuprofen should be borne in mind when prescribing ibuprofen together with other protein bound drugs which bind to the same site on human serum albumin.

Metabolism: About 90% of ibuprofen is metabolized to two major metabolites. Both metabolites are dextrorotatory and are devoid of anti-inflammatory and analgesic activity.

Excretion:

The kidney is the major route of excretion. 95% of ibuprofen was excreted in the urine within 24 hours of a single dose of 500 mg.

Half-life: Plasma half-life of ibuprofen is in the range 1.9 to 2.2 hours.

INDICATIONS: Rheumatoid arthritis, Osteoarthritis, Juvenile rheumatoid arthritis.

Primary dysmenorrhoea, Pyrexia.

Ibuprofen is also indicated for the relief of acute and/or chronic pain states in which there is an inflammatory component.

CONTRAINDICATIONS:

-Known hypersensitivity to ibuprofen or any of the inactive ingredients.

-Hypersensitivity (e.g. asthma, rhinitis or urticaria) to aspirin or other nonsteroidal anti-inflammatory drugs.

-History of gastrointestinal bleeding or perforation, related to previous NSAID therapy.

-History of, ulcerative colitis, Crohn's disease, recurrent peptic ulceration or gastrointestinal hemorrhage (defined as two or more distinct episodes of proven ulceration or bleeding).

-Severe heart failure. Severe liver failure.

-Severe renal failure (glomerular filtration below 30ml/min).

-Conditions involving an increased tendency to active bleeding.

-During the third trimester of pregnancy.

POSSIBLE SIDE EFFECTS:

The most common (greater than 1%) adverse effects reported include: nausea, epigastric pain, heartburn, diarrhea, abdominal distress, nausea and vomiting, dyspepsia, abdominal cramps or pain, constipation, gastrointestinal haemorrhage, haematemesis, flatulence, tinnitus, hearing impaired, oedema, edema, dizziness, headache, nervousness, decreased appetite, fatigue. Hypersensitivity reactions have also been reported following treatment with NSAIDs. These may include:

-Non-specific allergic reaction and anaphylaxis.

-Respiratory tract reactivity comprising asthma, bronchospasm or dyspnoea.

-Assorted skin disorders, including rashes, pruritus, urticaria, purpura, angioedema and more rarely, exfoliative and bullous dermatoses.

WARNINGS AND PRECAUTIONS:

CARDIOVASCULAR THROMBOTIC EVENTS:

Observational studies have indicated that non-selective non steroidal anti-inflammatory drugs (NSAIDs) may be associated with an increased risk of serious cardiovascular events, including myocardial infarction and stroke, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk factors may be at greater risk. To minimize the potential risk of an adverse cardiovascular event in patients taking an NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration. There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAIDs use. Also concurrent use of aspirin and NSAIDs does increase the risk of serious GI events.

GASTROINTESTINAL EVENTS:

Ibuprofen should be used with extreme caution, and at the lowest effective dose, in patients with history of gastrointestinal haemorrhage or ulcer since their condition may be exacerbated. All NSAIDs can cause gastrointestinal discomfort and serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. The concomitant administration of ibuprofen and other NSAIDs, including cyclooxygenase-2(Cox-2) selective inhibitors, should be avoided due to the increased risk of ulceration or bleeding. When gastrointestinal bleeding or ulceration occur in patients receiving NSAIDs, the drug should be withdrawn immediately.

Caution should be exercised in patients receiving concomitant medication which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin re-uptake inhibitors or antiplatelet drugs such as aspirin.

Hypertension: NSAIDs may lead to onset of new hypertension or worsening of pre-existing hypertension and patients taking anti-hypertensives with NSAIDs may have an impaired anti-hypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension and monitoring blood pressure when initiating therapy and regularly thereafter on long term treatment.

Heart Failure: Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

Respiratory Disorders: Caution is required if ibuprofen is administered to patients suffering from, or with a previous history of, bronchial asthma, chronic rhinitis or allergic diseases since ibuprofen has been reported to cause bronchospasm, urticaria or angioedema in such patients.

Impaired Liver Function or History of Liver Disease:

Patients with impaired liver function or history of liver disease who are on long term ibuprofen therapy should have hepatic function monitored at regular intervals. Ibuprofen has been reported to have a minor and transient effect on liver enzymes. Severe hepatic reactions, including jaundice and cases of fatal hepatitis, though rare, have been reported with ibuprofen as with other NSAIDs. If abnormal liver tests persist or worsen, or if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g. eosinophilia, rash, etc.), ibuprofen should be discontinued.

Impaired Renal Function:

Caution should be used when initiating treatment with ibuprofen in patients with considerable dehydration. There is a risk of renal impairment especially in dehydrated children and adolescents. In patients with renal, cardiac or hepatic impairment, those taking diuretics and ACE inhibitors, and the elderly, caution is required since the use of NSAIDs may result in deterioration of renal function. The long term concomitant intake of various analgesics further increases the risk. For patients with renal, hepatic or cardiac impairment, use the lowest effective dose, for the shortest possible duration and monitor renal function especially in long term treated patients.

Hematological Effects: Anemia is sometimes seen in patients receiving NSAIDs, including ibuprofen. Patients on long-term treatment with NSAIDs, including ibuprofen, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia.

NSAIDs inhibit platelet aggregation and have been shown to prolong bleeding time in some patients. Unlike aspirin, their effect on platelet function is quantitatively less, of shorter duration, and reversible.

Skin Reactions: NSAIDs, including ibuprofen, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. The drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Ophthalmological Effects: Blurred and/or diminished vision, scotoma, and/or changes in color vision have been reported. When such complications occur the drug should be discontinued.

Aseptic Meningitis: Aseptic meningitis with fever and coma has been observed on rare occasions in patients on ibuprofen therapy.

Anaphylactoid Reactions: As with other NSAIDs anaphylactoid reactions may occur in patients without known exposure to ibuprofen. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Emergency help should be sought in cases where an anaphylactoid reaction occurs.

Preexisting asthma: Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm, which can be fatal. Since cross reactivity, including bronchospasm between aspirin and NSAIDs has been reported in such aspirin-sensitive patients, ibuprofen should not be administered to patients taking this form of aspirin sensitivity and should be used with caution in patients with preexisting asthma. As with other NSAIDs, ibuprofen may mask the signs of infection.

DRUG INTERACTIONS: IBUPROFEN SHOULD NOT BE USED IN COMBINATION WITH:

-Aspirin (above 75mg daily): This may increase the risk of adverse reactions.

-Other NSAIDs: These may increase the risk of adverse reactions.

IBUPROFEN SHOULD BE USED WITH CAUTION IN COMBINATION WITH:

-ACE inhibitors: NSAIDs may diminish the antihypertensive effect of ACE inhibitors.

-Aspirin (as anti-aggregant): As with other NSAIDs, concomitant administration of ibuprofen and aspirin is not generally recommended because of the potential for increased adverse effects.

-Selective serotonin-reuptake inhibitors: may increase the risk of gastrointestinal bleeding.

-Corticosteroids: may increase the risk of adverse reactions, especially of the gastrointestinal tract.

-Cyclosporin: NSAIDs may increase the plasma concentration of cyclosporine and the risk of cyclosporine nephrotoxicity.

-Zidovudine: There is an evidence of an increased risk of haemarthroses and haematoma in HIV positive haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

-Diuretics: Ibuprofen can reduce the natriuretic effect of furosemide and thiazides in some patients.

-Anticoagulants (coumarin type): Bleeding has been reported when ibuprofen and other NSAIDs have been administered to patients on coumarin-type anticoagulants. The effects of warfarin and NSAIDs on GI bleeding are synergistic.

-Lithium: there is evidence for potential increase in plasma levels of lithium.

-Methotrexate: NSAIDs may enhance the toxicity of methotrexate.

-H₂ Antagonists: Co-administration of cimetidine or ranitidine with ibuprofen had no substantive effect on ibuprofen serum concentrations.

LACTATION:

During the first and second trimester of pregnancy, ibuprofen should not be given unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first or second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

Ibuprofen is contraindicated during the last trimester of pregnancy.

Ibuprofen is not recommended for use in nursing mothers.

FEMALE FERTILITY:

The use of ibuprofen may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of ibuprofen should be considered.

EFFECTS ON ABILITY TO DRIVE AND TO USE MACHINES:

Patients who experience dizziness, drowsiness, vertigo, or visual disturbances while taking ibuprofen, should avoid driving or using machinery. Single administration or short term use of ibuprofen does not usually warrant the adoption of special precautions.

DOSSAGE AND ADMINISTRATION:

For film coated tablet :
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The treating physician decides on the duration of treatment.

In rheumatic diseases the use of ibuprofen can be required for a longer period.

The ibuprofen dose depends on the patient's age and body weight. The maximum single dose for adults should not exceed 800 mg of ibuprofen.

The tablet should be swallowed with a glass of water preferably after a meal. It is recommended, that patients with a sensitive stomach take ibuprofen during a meal.

Mild to moderate pain and fever :

Adults and adolescents 240 kg body weight (12 years and above):

200-400 mg given as a single dose or 3-4 times a day with an interval of 6 hours as required.

The dosage in migraine headache should be: 400 mg given as a single dose, if necessary 400 mg with intervals up to 6 hours.

The maximum daily dose should not exceed 1200 mg.

Children 20 kg body weight (6-11 years):

Children 20-29 kg (6-9 years): 200 mg 1-3 times a day with intervals of 6 hours as required.

The maximum daily dose should not exceed 600 mg.

Children 30-90 kg (10-11 years): 200 mg 1-4 times a day with intervals of 6 hours as required.

The maximum daily dose should not exceed 800 mg.

Ibuprofen is contraindicated in children below 20 kg body weight or younger than 6 years of age
Primary dysmenorrhoea :

Adults and adolescents ≥40 kg body weight (12 years of age and above):

200-400 mg 1-3 times a day, with an interval up to 6 hours, as needed. The maximum daily dose should not exceed 1200 mg.

Rheumatic diseases : Adults:

The recommended dose is 1200-1800 mg daily in divided doses. Maintenance doses of 600 mg-1200 mg daily may be effective in some patients. In acute and severe conditions the dose may be (temporarily) increased to a maximum of 2400 mg in 3 or 4 divided doses.

Adolescents from 15 to 17 years of age:

The recommended dose should be adjusted by weight: 20 mg/kg to a maximum of 40 mg/kg body weight daily (max 2400 mg daily) in 3 to 4 divided doses.

Elderly : NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events and are at increased risk of potentially fatal gastrointestinal haemorrhage, ulceration or perforation. If treatment is considered necessary, the lowest dose for the shortest duration necessary to control symptoms should be used. Treatment should be reviewed at regular intervals and discontinued if no benefit is seen or intolerance occurs.

Impaired renal function:

In patients with mild or moderate reduction of renal function, the dose should be kept as low as possible for the shortest duration necessary to control symptoms and renal function monitored.

Impaired liver function :

In patients with mild or moderate reduction of liver function the dose should be kept as low as possible for the shortest duration necessary to control symptoms and liver function monitored.

For granules:

How to use: by emptying the contents of the sachet into a glass full of water to make an orange flavored fizzy drink, stir and drink immediately. Take with or after food.

For 600 mg:

Adults and Children over 12 years: The usual dosage is 1 sachet taken two or three times a day. The doctor may choose to increase or decrease this depending on what the patient being treated for, but no more than 4 sachets should be taken in one day.

For 200 - 400 mg:

Symptomatic treatment of fever and pain.
Adults and children over 12 years: 200 to 400 mg every 4 to 6 hours, not more than 1200 mg per day

Elderly: 200 mg every 4 to 6 hours. Children: a daily dose of 20 mg / kg is proposed. It is recommended no more than 400 mg / day (in different groups) should be administered to children weighing less than 30 kg.

Dysmenorrhoea: 400 mg, 3 times a day. The treatment starts as soon as the first symptom pain occurs or one days before the expected menstruation.

Especially in elderly people should seek treatment as soon as possible, and use the lowest dosage possible after the

For suspension :

Shake well before using.

100 mg / 5 ml Adult, the elderly and children over 12 years:

The recommended dose is 200 mg-400 mg (10-20 ml), up to three times a day as required.

Leave at least four hours between doses and do not take more than 1200 mg (60 ml) in any 24 hour period.

Children: For pain and fever – 20 mg/kg/day in divided doses (including OTC use).

Infants 3-6 months weighing more than 5 kg: One 2.5 ml dose may be taken 3 times in 24 hours. Do not use for more than 24 hours/infants 6 months-1 year: 2.5 ml three to four times a day, Children 1-4 years: 5 ml three times a day, Children 4-7 years: 7.5 ml three times a day, Children 7-12 years: 10 ml three times a day, Post-immunisation fever: 2.5 ml (50 mg) followed by one further dose of 2.5 ml (50 mg) six hours later if necessary. No more than 2 doses in 24 hours. If fever is not reduced, consult a doctor.

For Juvenile Rheumatoid Arthritis (prescription only use): Doses up to 30-40mg/kg/day may be taken in three or four divided doses.

Do not give to children under 3 months of age.

For infants aged 3 - 5 months medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist.

If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen a doctor should be consulted.

200mg/5ml:

The recommended dose is:

Age	AgHow much
Under seven years	Do not use
Seven - nine years	One 5ml dose up to three times in 24 hours
Ten - twelve years	One 5ml dose and one 2.5ml dose up to three times in 24 hours
Do not give to children under 7 years of age or those weighing less than 20kg	
Separate the doses evenly (every 6-8 hours). Leave at least 4 hours between doses	
Do not give more than 3 doses in any 24 hour period.	

Duration of treatment

This product is intended for short term use only. You must talk to your doctor or pharmacist if your child does not get better or feels worse after three days.

For suspension (oral drops): Direct use. Shake well before using The dose could be repeated every 6 hours if necessary. But not more than 4 times a day.

Pediatric Patients: Fever Reduction: In children, 6 months up to 2 years of age, the dosage should be adjusted on the basis of the initial temperature level. The recommended dose is 5 mg/kg if the baseline temperature is less than 39°C, or 10 mg/kg if the baseline temperature is 39°C or greater. The duration of fever reduction is generally 6 to 8 hours. The recommended maximum daily dose is 40 mg/kg.

Analgesia: For mild to moderate pain in children 6 months up to 2 years of age, the recommended dosage is 10 mg/kg, every 6 to 8 hours. The recommended maximum daily dose is 40 mg/kg. Doses should be given so as not to disturb the child's sleep pattern.

Juvenile Arthritis: The recommended dose is 30 to 40 mg/kg/day divided into three to four doses. Patients with milder disease may be adequately treated with 20 mg/kg/day. In patients with juvenile arthritis, doses above 50 mg/kg/day are not recommended because they have not been studied and doses exceeding the upper recommended dose of 40 mg/kg/day may increase the risk of causing serious adverse events. The therapeutic response may require from a few days to several weeks to be achieved. Once a clinical effect is obtained, the dosage should be lowered to the smallest dose of Ibuprofen Oral Suspension needed to maintain adequate control of symptoms. Pediatric patients receiving doses above 30 mg/kg/day or if abnormal liver function tests have occurred with previous NSAID treatments should be carefully followed for signs and symptoms of early liver dysfunction.

Suppositories: Rectal use. Use in children under 6 months of age requires prescription.

For short term use only.

Do not use this product in children under 3 months of age without medical advice.

Do not use this product in children weighing less than 6 Kg.

Ibuprofen suppositories 125 mg are not suitable for infants weighing less than 12.5 kg

(approximately 2 years of age), as suppositories containing less active substance are needed.

Age	Bod Weight(kg)	Recommended Dosage
Infants 3-9 months weighing more than 6 kg	6-8	60 mg up to 3 times in 24 hours, leaving 6-8 hours between doses
9 months-2 years	8-12.5	60 mg up to 4 times in 24 hours, leaving 6 hours between doses
Children 2-4 years	12.5-17	125 mg up to 3 times in 24 hours, leaving 6-8 hours between doses
Children 4-7 years	17-20.5	125- 150 mg up to 4 times in 24 hours, leaving 6 hours between doses
Children 7- 12 years		200-300 mg up to 3 times in 24 hours
12 – 18 years		300- 400 mg up to 3-4 times in 24 hours.

Dosage not exceed 2.4g in 24 hours.

For infants aged 3-5 months, medical advice should be sought if symptoms worsen or not later than 24 hours if symptoms persist. If in children aged from 6 months and in adolescents this medicinal product is required for more than 3 days, or if symptoms worsen, a doctor should be consulted.

Chewable tablets:

Repeat dose every 6-8 hours, if needed. Do not use more than 4 times a day.

Children 6- 8 years: 2 tablets. Children 9 - 10 yr: 2½ tablets. 11 yr : 3 tablets.

For the suspension (single dose sachet):

(50 mg/2.5 ml, 100 mg/5 ml, 150 mg/7.5 ml, 200 mg/10 ml, 300 mg/15 ml):

Recommended dosage:

High fever after vaccinations (child weight ≥ 5 kg, age ≥ 3 months):

One sachet of 50 mg/2.5 ml, up to twice daily.

In necessary cases, the second dose may be given 6 hours after the first one.

Do not give more than 2 doses in a 24 hour period

Do not give any more medicine after the second dose.

See a doctor if fever continues.

Fever, pain, and cold symptoms:

Child's age & weight	Dosage	Frequency within 24 h
3–6 months (≥ 5 kg)	50 mg/2.5 ml – one sachet	3 times (not more than 1day)
6–12 months (7–10 kg)	50 mg/2.5 ml – one sachet	3–4 times
1–3 years (10–15 kg)	100 mg/5 ml – one sachet	3 times
4–6 years (15–20 kg)	150 mg/7.5 ml – one sachet	3 times
7–9 years (20–30 kg)	200 mg/10 ml – one sachet	3 times
10–12 years (30–40 kg)	300 mg/15 ml – one sachet	3 times

Important instructions:

Do not use for more than 6-8 hours, with at least 4 hours between doses.

Do not give to infants under 3 months unless prescribed by a doctor.

Short-term use only:

Do not use for children aged 3–6 months for more than 24 hours.

Do not use for children aged 6 months and older for more than 3 days.

Consult a doctor if symptoms worsen or persist.

Give the lowest effective dose for the shortest possible time to relieve the symptoms.

Do not give more than the amount recommended above.

(400 mg/10 ml): Adults and adolescents over 12 years (weight > 40 kg): Recommended dose: One sachet up to 3 times daily as needed, leaving 4–6 hours between doses. Do not take more than 3 sachets per day.

Note: The sachet contents should be mixed before administration by pressing the top and bottom of the sachet several times with the fingers.

The medicine can be taken directly from the sachet.

The sachet can not be divided between doses and should be taken as a whole..

For faster onsetof action, the medicine may be taken on an empty stomach. If the patient has a sensitive stomach, it should be taken with food.

OVERDOSAGE: SYMPTOMS:

Headache, nausea, abdominal pain and vomiting,

gastrointestinal bleeding.

Rarely:diarrhea,disorientation,excitation,drowsiness,dizziness,tinnitus,fainting, depression of the CNS and the respiratory system, coma, occasionally convulsions and rarely, loss of consciousness. In cases of significant poisoning, acute renal failure and liver damage are possible.

MANAGEMENT: There is no specific antidote to ibuprofen.

The treated patient should be monitored and supportive care include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Activated charcoal should be considered if the patient is presented within 1 hour of ingestion of a potentially toxic amount. The patient should be observed for at least four hours after ingestion of a potentially toxic amount. Hepatic and renal function should be controlled. Frequent or prolonged convulsions should be treated with intravenous diazepam. Give bronchodilators for asthma.

STORAGE: Store at a temperature below 25°C, away from heat and out of reach of children.

PRESENTATION: Opaque glass bottle with a capacity of 100 ml.

THIS IS A MEDICAMENT

A medicament is a Product but Unlike any Other Products

A medicament is a Product Which Affects Your health, and its Consumption Contrary to instructions is Dangerous for you.

Follow Strictly the Doctors' prescription, the Method of use and the Instructions of the Pharmacist who Sold the Medicament. The Doctor and the Pharmacist are Experts in Medicine, its Benefits and Risks.

Do not by Yourself Interrupt the Period of Treatment Prescribed for you.

Do not Repeat the Same Prescription Without Consulting your Doctor.

Keep Medicaments out of Reach of children

(Cauncil of Arab Health Ministers)